REMARKS

Claims 15-28 are pending in the above-identified application.

Unity of Invention Requirement Issues

The Office Action of July 16, 2007 indicates that the Patent Examiner maintained the Unity of Invention Requirement and Species Election. The Examiner has also requested that Applicant reaffirm the previously made elections.

First, Applicants reaffirm the election of subject matter of Group I, i.e. claims 15-18, as well as the elected species which is the compound 2-methyl-6-(phenylethynyl)-pyridine (MPEP). These elections were made with traverse, and Applicants maintain the traversal for the reasons previously indicated in the Response filed June 18, 2007. In addition, it is respectfully submitted that the "Species Election" was provisionally made for the purpose of initiating substantive examination and Applicants do not intent to restrict the scope of the present invention to the use of the single compound (MPEP). Rather, the present invention is directed to the use of mGluR5 antagonists for the inhibition of transient lower esophageal sphincter relaxations (TLESRs), and thus for the treatment of gastro-esophageal reflux disease (GERD). Consequently, it is respectfully requested that the Examiner reconsider the Unity of Invention Requirement and Species Election.

"Enablement" Issues

Claims 17, 18, 24, 25 and 28 have been rejected under 35 USC 112, first paragraph, as allegedly failing to satisfy the enablement requirement. The Office Action states that there is inadequate support for the use of the term "prevention" in the rejected claim and cites the case *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988) in support of the insertion that one skilled in the art would be required to conduct an unreasonably large quantity of experimentation in order to practice the present invention.

In response to the above-noted positions stated in the Office Action, it is first submitted that the experimental data provided in the present application clearly supports the conclusion that mGluR5 antagonist can be used for the inhibition of TLESRs and thereby for the treatment of GERD. The result of inhibiting TLESRs in a subject would clearly result in the treatment of GERD, or the prevention of GERD if this disorder has not already occurred. Please refer to the scientific publication Holloway & Dent (1990) *Gastroenterol. Clin. N. Amer.*, 19, pp. 517-535, which is cited in the present specification and which was submitted with an Information Disclosure Statement filed on June 28, 2007. This publication evidences the fact that most reflux episodes occur during TLESRs, i.e. relaxations not triggered by swallows. This publication confirms the direct relationship between TLESRs and GERD. This publication also clarifies that TLESRs is the predominant cause of GERD. Consequently, a person skilled in the art would not require any unnecessary quantity of experimentation in order to practice the present invention since it is clear that mGluR5 antagonists would inhibit TLESRs so as to treat or prevent GERD. Thus, it is respectfully requested that the above-noted rejection be withdrawn.

"Written Description" Requirement Issues

Claims 15-18, 24, 25 and 28 have been rejected under 35 USC 112, first paragraph, as alleging failing to comply with the written description requirement. Specifically, the Office Action asserts that various etiologic factors, other than mGluR5 antagonist, may cause TLESRs, GERD, reflux and regurgitation, such that the inhibition of TLESRs shown by the animal model data does not necessary result in the inhibition of GERD, reflux or regurgitation. Rather, factors other than those resulting in TLESRs inhibition can cause GERD, reflux and regurgitation disorders, such that Applicants have failed to show "possession" of the claimed invention. This rejection is traversed based on the following reasons.

First, it is respectfully submitted that the above-noted Holloway & Dent publication clearly establishes that TLESRs is the predominant cause of GERD. Thus, TLESRs is the predominant mechanism for gastroesophageal reflux. Reflux is a condition where the gastric

juice travels back from the stomach into the esophagus. Symptoms of gastroesophageal reflux include regurgitation. When patients experience this regularly, it is called gastroesophageal reflux disease (GERD). Symptoms of GERD include failure to thrive, regurgitation, lung disease and chronic laryngitis. Consequently, there is a direct and clear relationship among the medical disorders recited in the present claims and described in the present application. Further, it is submitted that the experimental test data summarized in the Examples described at pages 9-13 of the present specification further support the present claims, especially claims 24-27 which recite specific compounds employed in the experiments. Therefore, Applicants were clearly in possession of the invention at the time of the filing of the present application, since the relationship between TLESRs and GERD was established. The present application also included experimental data clearly demonstrating that the use of mGluR5 antagonists provided for the inhibition of TLESRs and thus the treatment or prevention of GERD. In view of these reasons it is requested that the above-noted rejection be withdrawn.

Conclusion

In conclusion, it is submitted that the problem underlying the discovery of the present invention was to find a new and improved way to provide for the inhibition of TLESRs, and thereby a new method for treating GERD. The solution to this problem was to use mGluR5 antagonists for the inhibition of TLESRs, and thereby to treat and prevent GERD. It is noted that there was no disclosure or suggestion whatsoever in the prior art indicating that it might be possible to use an mGluR5 antagonist for the inhibition of TLESRs, and thereby to treat and prevent GERD. Since the present invention describes an entirely new approach to the therapy of GERD, it would be unreasonable that Applicants would have to be required to limit the scope of the claims to the use of specific compounds limited to those tested in the examples described in the present specification. In this regard, it is noted that it is not required that the specification include "working" examples to support the full scope of the patent claims. *In re Borkowski*, 164 USPQ 642, 645 (CCPA 1970). Clearly, all of the mGluR5 antagonists have not been tested for the presently claimed medical use. However, based on the information in the present

application, a person skilled in the art would be able to conclude that all mGluR5 antagonist would be effective for this use.

If any questions arise in the above matters, please contact Applicant's representative, Andrew D. Meikle (Reg. No. 32,868), in the Washington Metropolitan Area at the phone number listed below.

If necessary, the Commissioner is hereby authorized in this, concurrent, and future replies, to charge payment or credit any overpayment to Deposit Account No. 02-2448 for any additional fees required under 37 C.F.R. §§ 1.16 or 1.17; particularly, extension of time fees.

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Respectfully submitted,

By _____
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